

N. M. M & O Docket No. P564-9C08

NIKAIDO, MARMELESTEIN, MURRAY & ORAM LLP

Declaration For U.S. Patent Application

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

(Insert Title) **HELICOBACTER PYLORI LIVE VACCINE**

the specification of which is attached hereto unless the following box is checked:

☒ was filed on September 1, 1997 as PCT International Application Number PCT/EP97/04744 and was amended on

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claim(s), as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. §1.56.

I hereby claim foreign priority benefits under 35 U.S.C. §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate or PCT International Application having a filing date before that of the application(s) for which priority is claimed:

(List prior foreign applications. See note A on back of this page)	<u>96116337.5</u>	<u>EP</u>	<u>11 October 1996</u>	Priority Claimed <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
	(Number)	(Country)	(Day/Month/Year Filed)	
	(Number)	(Country)	(Day/Month/Year Filed)	
	(Number)	(Country)	(Day/Month/Year Filed)	

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below.

(Application Number)	(Filing Date)
(Application Number)	(Filing Date)

(See Note B on back of this page)

☐ See attached list for additional prior foreign or provisional applications.

I hereby claim the benefit under 35 U.S.C. §120 of any United States application(s) or §365(c) of any PCT International application(s) designating the United States of America listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior application(s) (U.S. or PCT) in the manner provided by the first paragraph of 35 U.S.C. §112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. §1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application.

(List prior U.S. Applications or PCT International applications designating the U.S.)	(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
	(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

And I hereby appoint as principal attorneys: David T. Nikaido, Reg. No. 22,663; Charles M. Marmelstein, Reg. No. 25,895; George B. Oram, Jr., Reg. No. 27,931; Robert B. Murray, Reg. No. 22,980; E. Marcio Emas, Reg. No. 32,131; Douglas H. Goldbush, Reg. No. 33,125; Monica Chin Kitta, Reg. No. 36,105; Richard J. Berman, Reg. No. 39,102; King L. Wong, Reg. No. 37,400; Karen K. Costantino, Reg. No. 35,107; James A. Poulos, III, Reg. No. 31,714; Herbert C. Ross, Reg. No. 29,846; and Patrick D. Muir, Reg. No. 37,409.

Please direct all communications to the following address: **NIKAIDO, MARMELESTEIN, MURRAY & ORAM LLP**
Metropolitan Square
635 Fifteenth Street, N.W., Suite 330 - G Street Lobby
Washington, D.C. 20003-5701
(202) 638-5000 Fax: (202) 638-4810

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

(See Note C on back of this page)

Full name of sole or first inventor: **Thomas P. MEYER**Inventor's signature XResidence: **Spemannstrasse 30, D-72076 Tübingen, Germany**Citizenship: **German**Post Office Address: **Same as above**

Date

Declaration For U.S. Patent Application

As a below named inventor, I hereby declare that:
 My residence, post office address and citizenship are as stated below my name.
 I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled
 (Insert Title) **HELICOBACTER PYLORI LIVE VACCINE**
 the specification of which is attached hereto unless the following box is checked:

☐ was filed on September 1, 1997 as PCT International Application Number PCT/EP97/04743 and was amended on

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claim(s), as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. §1.56. I hereby claim foreign priority benefits under 35 U.S.C. §119(a)-(d) or §365(b) or any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate or PCT International Application having a filing date before that of the application(s) for which priority is claimed:

(List prior foreign applications. See note A on back of this page)	<u>9616337.3</u> (Number)	<u>EP</u> (Country)	<u>11 October 1996</u> (Day/Month/Year Filed)	Priority Claimed a Yes <input type="checkbox"/> No
	<u></u> (Number)	<u></u> (Country)	<u></u> (Day/Month/Year Filed)	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<u></u> (Number)	<u></u> (Country)	<u></u> (Day/Month/Year Filed)	<input type="checkbox"/> Yes <input type="checkbox"/> No

I hereby claim the benefit under 35 U.S.C. §115(b) of any United States provisional application(s) listed below.

<u></u> (Application Number)	<u></u> (Filing Date)
<u></u> (Application Number)	<u></u> (Filing Date)

(See Note D on back of this page) ☐ See attached list for additional prior foreign or provisional applications.

I hereby claim the benefit under 35 U.S.C. §120 of any United States application(s) or §365(c) of any PCT International application(s) designating the United States of America listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior application(s) (U.S. or PCT) in the manner provided by the first paragraph of 35 U.S.C. §112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. §1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application.

(List prior U.S. Application or PCT International applications designating the U.S.)	<u></u> (Application Serial No.)	<u></u> (Filing Date)	<u></u> (Status) (patented, pending, abandoned)
	<u></u> (Application Serial No.)	<u></u> (Filing Date)	<u></u> (Status) (patented, pending, abandoned)

And I hereby appoint as principal attorneys: David T. Nikaido, Reg. No. 22,663; Charles M. Marmelestein, Reg. No. 25,892; George E. Oram, Jr., Reg. No. 27,931; Robert B. Murray, Reg. No. 22,980; E. Marcia Ennes, Reg. No. 32,131; Douglas H. Goldbush, Reg. No. 33,125; Monica Chin Kitts, Reg. No. 36,103; Richard J. Beriman, Reg. No. 39,107; King L. Wang, Reg. No. 37,500; Karen K. Costantino, Reg. No. 35,107; James A. Poules, III, Reg. No. 31,714; Herbert C. Rose, Reg. No. 29,346; and Patrick D. Muir, Reg. No. 37,403.

Please direct all communications to the following address:
 NIKAIKO, MARMELESTEIN, MURRAY & ORAM LLP
 Metropolitan Square
 605 Fitzsimons Street, N.W., Suite 330 - G Street Lobby
 Washington, D.C. 20005-5701
 (202) 638-5000 Fax: (202) 638-4810

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

(See Note C on back of this page)

Full name of sole or first inventor: Thoralf F. MEYER

Inventor's signature: [Signature]

Residence: Spemannstrasse 30, D-72076 Tübingen, Germany

Citizenship: German

Post Office Address: Same as above

Date

X 22.6.99

Second page coded

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2-00

Full name of second joint inventor, if any: Rainer HAAS

Inventor's signature X

Residence: WENINGSTR. 12, D-81547 MÜNCHEN DEX

Citizenship: German

Post Office Address: Same as above

Full name of third joint inventor, if any: Yan ZHENGXIN

Inventor's signature X

Residence: Pflichtenweg 6, D-72076 Tübingen, Germany

Citizenship: Chinese

Post Office Address: Same as above

4-00

Full name of fourth joint inventor, if any: Carlos GOMEZ DUARTE

Inventor's signature X

Residence: Edward Spranger Straße 14, D-72076 Tübingen, Germany

Citizenship: Columbian

Post Office Address: Same as above

Full name of fifth joint inventor, if any: Bernadette LUCAS

Inventor's signature X

Residence: Edward Spranger Straße 14, D-72076 Tübingen, Germany

Citizenship: French

Post Office Address: Same as above

5-00

Karl-Stieler Str. 3

061

12167 BERLIN

DEX

Full name of second joint inventor, if any: Rainer HAAS

Inventor's signature X

Date

Residence: Uratiner Ring 65, D-72076 Tübingen, Germany

Citizenship: German

Post Office Address: Same as above

Full name of third joint inventor, if any: Yan ZHENOXIN

Inventor's signature X

Date

Residence: Fichtenweg 6/403, D-72076 Tübingen, Germany DEX

Citizenship: Chinese

Post Office Address: Same as above Fichtenweg 6/403, D-72076 Tübingen, FRG

Full name of fourth joint inventor, if any: Oscar GOMEZ-DUARTE

Inventor's signature X

Date

Residence: Eduard-Spranger-Strasse 34, D-72076 Tübingen, Germany

Citizenship: Columbian

Post Office Address: Same as above

Full name of fifth joint inventor, if any: Bernadette LUCAS

Inventor's signature X

Date

Residence: Eduard-Spranger-Strasse 34, D-72076 Tübingen, Germany

Citizenship: French

Post Office Address: Same as above

3-00

Serial or Patent No. _____ Docket No.: _____

Filed or Issued: _____

To: _____

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) and 1.27(c) - SMALL BUSINESS CONCERN)

I hereby declare that I am

- () the owner of the small business concern identified below:
(X) an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN Creatogen Biosciences GmbH

ADDRESS OF CONCERN Ulmer Straße 160a, D-86156 Augsburg, Germany

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled Helicobacter pylori live vaccine by Inventor(s) Thomas F. Meyer, Rainer Haas, Yan Zhengxin, Oscar Gomez-Duarte, Bernadette Lucas described in _____

- (X) the specification filed herewith
() application serial no. _____ filed _____
() patent no. _____, issued _____

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(d) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e). NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME _____

ADDRESS _____

() INDIVIDUAL () SMALL BUSINESS CONCERN () NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28 (b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING Dr. Ian P. Thrippleton

TITLE OF PERSON OTHER THAN OWNER CEO

ADDRESS OF PERSON SIGNING Ulmer Straße 160a, D-86156 Augsburg, Germany

SIGNATURE [Signature] DATE March 30, 1999

Applicant or Patentee: _____

Attorney's
Docket No.: _____

Serial or Patent No. _____

Filed or Issued: _____

For: _____

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) and 1.27 (d) - NONPROFIT ORGANIZATION)

I hereby declare that I am an official empowered to act on behalf of the nonprofit organization identified below:

NAME OF ORGANIZATION Max-Planck-Gesellschaft zur Förderung der
ADDRESS OF ORGANIZATION Wissenschaften e.V.
Hofgartenstraße 2, D-80539 München, Germany

TYPE OF ORGANIZATION

- ☐ UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION
☐ TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 USC 501(a) and 501 (c) (3))
☐ NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA
(NAME OF STATE _____)
(CITATION OF STATUTE _____)
☒ WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 USC 501(a) AND 501(c) (3) IF LOCATED IN THE UNITED STATES OF AMERICA
☐ WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF THE UNITED STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA
(NAME OF STATE _____)
(CITATION OF STATUTE _____)

I hereby declare that the nonprofit organization identified above qualifies as a nonprofit organization as defined in 37 CFR 1.9(e) for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code with regard to the invention entitled Helicobacter pylori live vaccine by inventor(s) Thomas F. MEYER, Rainer HAAS, Yan ZHENGXIN, Oscar GOMEZ-DUARTE, Bernadette LUCAS described in

- ☒ the specification filed herewith
☐ application serial no. _____, filed _____
☐ patent no. _____, issued _____

I hereby declare that rights under contract or law have been conveyed to and remain with the nonprofit organization with regard to the above identified invention. If the rights held by the nonprofit organization are not exclusive, each individual, concern or organization having rights to the invention is listed below * and no rights to the invention are held by any person, other than the inventor, who could not qualify as small business concern under 37 CFR 1.9 (d) or by any concern which would not qualify as a small business concern under 37 CFR 1.9 (d) or a nonprofit organization under 37 CFR 1.9(e). * NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME Creatogen Biosciences GmbH
ADDRESS Ulmer Straße 160a, D-86156 Augsburg, Germany
☐ INDIVIDUAL ☒ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

NAME _____
ADDRESS _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING Dr. Heinrich Kuhn
TITLE IN ORGANIZATION Head of patent department
ADDRESS OF PERSON SIGNING Hofgartenstr. 8, 80539 München
SIGNATURE Dr. Heinrich Kuhn